



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,449	02/28/2002	Michael L. Blomquist	4176.25US01	9068

24113 7590 11/08/2010
PATTERSON THUENTE CHRISTENSEN PEDERSEN, P.A.
4800 IDS CENTER
80 SOUTH 8TH STREET
MINNEAPOLIS, MN 55402-2100

EXAMINER

NORTON, JENNIFER L

ART UNIT	PAPER NUMBER
----------	--------------

2121

MAIL DATE	DELIVERY MODE
-----------	---------------

11/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/087,449	Applicant(s) BLOMQUIST, MICHAEL L.	
	Examiner JENNIFER L. NORTON	Art Unit 2121	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The following is a **Final Office Action** in response to the Amendment/Remarks received on 12 October 2010. Claims 1-25 are pending in this application.

Response to Arguments

2. Applicant's arguments, see Remarks pgs. 10-13, filed 12 October 2010 with respect to claims 1-25 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

3. Applicant argues that the prior art fails to teach, "each cell in the row relating to a different operating parameter for the delivery program." The Examiner respectfully disagrees.

The Examiner has further clarified the rejection of claims 1 and 12 with respect to the limitation of "each cell in the row relating to a different operating parameter for the delivery program".

In addition, the reference of Estes (U.S. Patent Publication No. 2003/0114836 A1) teaches "FIG. 3A illustrates how **the settings 300** of the bolus estimator 128 **may be fixed or variable**. One or more of these settings (e.g., the carbohydrate ratio, target blood glucose and insulin sensitivity), can follow a profile that changes over the course of a day. FIG. 3A shows example profiles for the carbohydrate ratio 302 and insulin sensitivity 304 values that vary over a daily schedule. Using these profiles enables the bolus estimator 128 to provide a more accurate estimate of the appropriate amount of insulin for a patient at a given moment. Different profiles can also be used for different days. In general, profiles can be generated to account for the anticipated activities of the patient

which affect the medication needs of the patient. For example, a workday profile may be different than a weekend day profile. Days during which the patient plans to exercise can have a different profile than days spent at rest. In addition profiles can also be created for different lengths of time. For example, a weeklong profile can be created around a patient's default routine. Short duration profiles to accommodate unplanned activities can then be inserted as necessary." (pg. 6, par. [0064])

Fig. 3A:

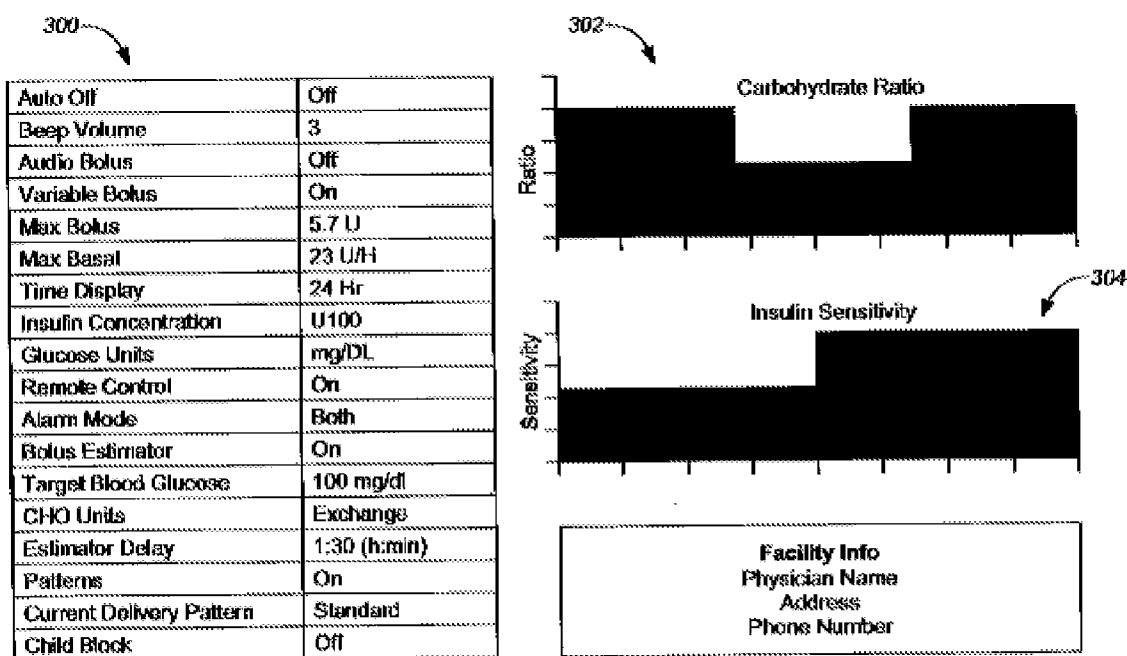


FIG. 3A

In summary, Estes teaching of the table of Fig. 3A containing a plurality of different operating parameters (i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3) inputted into a row of cells for a delivery program, meets Applicant's claimed limitation of "each cell in the row relating to a different operating parameter for the delivery program".

Art Unit: 2121

4. With respect to Applicant argument that the prior art fails to teach, "the operating parameters vary between data sets." The Examiner respectfully disagrees.

The Examiner has further clarified the rejection of claim 8 with respect to the limitation "the operating parameters vary between data sets".

In addition, the reference of Karmiy (U.S. Patent Publication No. 2003/0069650 A1) teaches "The system 100 also includes a store of operations 110 (including operations 110a-e), **a store of procedures 112 (including procedures 112a-c)**, and a configuration file 114. Each one of operations 110 includes a sequence of one or more steps that may be executed by a programmable logic controller 116 in conjunction with the control of the chemical process machine 118. For example, referring to FIG. 2, an example of the structure of operation 110a is shown in more detail. As shown in FIG. 2, operation 110a includes a sequence of n steps 202a-n. The number of steps n may be any number and is often in the hundreds or thousands. Different ones of the operations 110 may have different numbers of steps. Examples of the steps 202a-n are described in more detail below." (pg. 2, par. [0026])

"The "Value" field 304h specifies a value that is associated with the "Action" field 304g of the step. For example, if the action performed by a step is to set an alarm, the "Value" field 304h may specify a value at which the alarm is to be triggered (i.e., an alarm limit). The type and range of values that may be provided in the "Value" field 304h of a step may vary depending upon the action to be performed by the step. In general, the "Value" field 304h may be seen as providing a value that further specifies the action to be performed by the step." (pg. 3, par. [0034])

"The "EGU" field 304i of a step specifies the engineering units associated with the "Value" field 304h, if any. For example, referring to FIG. 3, it can be seen that the value of the "EGU" field 304i of step 302a is "psig," indicating that the units of the value -10 is psig. Not all actions may require or allow a value to be provided for the "EGU" field 304i." (pg. 3, par. [0035])

Art Unit: 2121

"Upon making any desired changes to the variable steps 504a-e, the user may save the changes to the current procedure by clicking on an "OK" button 510 or cancel the changes by clicking on a "Cancel" button 512. If the user saves the changes to the current procedure, the changes are saved to the current procedure (such as by modifying a procedure data structure described below with respect to FIG. 6) without affecting other procedures that incorporate the current operation, as described in more detail below." (pg. 5, par. [0058])

In summary, Karmiy teaches to one of a plurality of procedures (i.e. Fig. 1, element 112a-112c) containing data comprising the same operating parameters (i.e. Fig. 3, element 304h and 304i; i.e. an alarm value and engineering units) where different procedures contain different values for the same type of operating parameters via editing/creating and saving parameters of one procedure without effecting another procedure's parameters; hence, Karmiy meets the Applicant's claimed limitation of "the operating parameters vary between data sets".

5. With respect to Applicant's argument that the prior art does not expressly teach ""selecting the user-defined identifying name thereby assigning the set of operating parameters identified by the user-defined identifying name to the delivery program," as required by claim 12."

The Examiner recognizes the Applicant has presented arguments against the references individually, wherein one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references.

Art Unit: 2121

See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

6. Claims 1-25 stand rejected under 35 U.S.C. 103(a) as set forth below.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2003/0114836 A1 (hereinafter Estes) in view of U.S. Patent Publication No. 2003/0069650 A1 (hereinafter Karmiy).

9. As per claim 1, Estes teaches a method of programming an ambulatory infusion pump (Fig. 1, element 100) from a computer (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the ambulatory infusion pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program being driven by operating parameters (pg. 3, par. [0032] and [0033]), the method comprising:

generating data (Fig. 3A, element 300) on an interface displayed by the computer the computer having a computer peripheral (col. 6, par. [0054]), the data

(Fig. 3A) contained in a row (pg. 6, par. [0054]; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), and each cell in the row relating to a different operating parameter for the delivery program (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3); and

downloading the operating parameters into the pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

Estes teaches a user interface displayed (Fig. 3B-3D) by the computer the computer having a computer peripheral (pgs. 2-3, par. [0027] and pg. 6, par. [0056]) but does not expressly teach generating a table on a user interface displayed by the computer the computer having a computer peripheral, the table containing a row, the row having a plurality of cells, each cell in the row relating to a different operating parameter for the delivery program; entering an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral.

Karmiy teaches generating a table (Fig. 3; i.e. a spreadsheet including row and columns) on a user interface (Fig. 1, element 104 and 106) displayed by the computer (Fig. 2, par. [0025] and pg. 3, par. [0028]) the computer having a computer peripheral (i.e. 8, par. [0078], [0079] and [0086]; i.e. an input device to provide a user with the ability to enter data/information into cells of the table), the table containing a row (Fig.

Art Unit: 2121

3, element 302a-302g), the row having a plurality of cells (Fig. 3, element 304a-304j), cells in the row relating to a different operating parameter for the delivery program (pg. 3, par. [0034]-[0035] and Fig. 3, element 304h and 304i); and

entering an operating parameter into at least one of the cells in the table (pg. 8, par. [0086]), the operating parameter being entered directly into the at least one of the cells through the computer peripheral (pg. 8, par. [0078] and [0079]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include generating a table on a user interface displayed by the computer, the table containing a row, the row having a plurality of cells, cells in the row relating to a different operating parameter for the delivery program; and entering an operating parameter into at least one of the cells in the table, the operating parameter being entered directly into the at least one of the cells through the computer peripheral to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

10. As per claim 8, Estes teaches a method of operating a pump (Fig. 1, element 100), the pump having a memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) and a pump mechanism (pg. 3, par. [0029]), the method comprising:

receiving from a computer, a plurality of data sets, each data set in the plurality of data sets containing a plurality of operating parameters (Fig. 3A, element 300; Fig. 2,

Art Unit: 2121

elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage"),

storing the plurality of data sets in memory (pgs. 3-4, par. [0035] and Fig. 1, element 106);

selecting one of the plurality of data sets (pg. 8, par. [0008] and Fig. 6, i.e. SUSPEND, BOLUS, BASAL); and

running a delivery program wherein the delivery program executes the operating parameters in the selected one of the plurality of data sets, the operating parameters defining a delivery schedule for controlling the pump mechanism (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes does not expressly teach wherein each data set in the plurality of data sets contains the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter.

Karmiy teaches wherein each data set (Fig. 1, element 112a-112c; i.e. one of a plurality of procedures containing data) in the plurality of data sets (pg. 2, par. [0026], pg. 6, par. [0062] and Fig. 1, element 112a-112c; i.e. a plurality of procedures

Art Unit: 2121

containing data) comprising the same type of operating parameters (pg. 3, par. [0034] and [0035] and Fig. 3, element 304h and 304i; i.e. an alarm value and engineering units) and at least two of the data sets (pg. 2, par. [0026] and Fig. 1, element 112a-112c) contain different values for the same type of operating parameter (pg. 3, par. [0034] and pg. 5, par. [0058] and Fig. 3, element 304h; i.e. different procedures contain different values for the same type of operating parameters via editing/creating and saving parameters of one procedure without effecting another procedure's parameters).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include wherein data sets comprising the same type of operating parameters and at least two of the data sets contain different values for the same type of operating parameter to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

11. As per claim 9, Estes teaches an apparatus (Fig. 2, element 132) for programming an infusion pump (pgs. 2-3, par. [0027]), pgs. 3-4, par. [0034] and [0035] and Fig. 1, element 100), the pump programmed to execute a delivery program (pgs. 3-4, par. [0034]), the delivery program programmed to process operating parameters (pg. 3, par. [0032] and [0033]), the operating parameters defining

operation of the pump (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), the apparatus comprising:

- a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop);

- a data entry device (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop); and

- a processor in data communication with the data port and the data entry device (pg. 3, par. [0034]; e.g. PC, laptop),

- data (Fig. 3A, element 300), the data contained in a row, the row having a plurality of cells (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), each cell in the row relating to a different operating parameter for the delivery program (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3);

- (b) display the data in one or more of the cells (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300); and

- (c) download the received operating parameters displayed (col. 6, par. [0054]) in the cells to the infusion pump (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

Estes does not expressly teach the processor programmed to generate a table; and receiving at least one operating parameter directly from the data entry device to the one or more cells.

Karmiy teaches a processor (Fig. 1, element 102) programmed to generate a table (pg. 2, par. [0025] and pg. 3, par. [0028]; via Fig. 1, element 104 and 106), the table containing a row (Fig. 3, element 302a-302g), the row having a plurality of cells (Fig. 3, element 304a-304j), cells in the row relating to a different operating parameter for the delivery program (pg. 3, par. [0034]-[0035] and Fig. 3, element 304h and 304i); and

receiving at least one operating parameter directly from the data entry device to the one or more cells (pg. 8, par. [0086], the operating parameter being entered directly into the at least one of the cells through the computer peripheral (pg. 8, par. [0078] and [0079]).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a processor programmed to generate a table, the table containing a row, the row having a plurality of cells, cells in the row relating to a different operating parameter for the delivery program; and receiving at least one operating parameter directly from the data entry device to the one or more cells to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

12. Claims 2-7, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes in view of Karmiy in further view of U.S. Patent Publication No. 2003/0011646 A1 (hereinafter Levine).

13. As per claim 2, Estes teaches the table comprising a plurality of rows (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3).

Estes does not expressly teach each row relating to a different set of operating parameters, each set of operating parameters defining a different delivery schedule for the pump.

Karmiy teaches each row (pg. 2, par. [0029] and Fig. 3, element 302a-302g) relating to a different set of operating parameters (pg. 2, par. [0034] and [0035] and Fig. 3, element 304h and 304i), each set of operating parameters defining a different operation for the device (pg. 2, par. [0029]).

Karmiy does not expressly teach each set of parameters defining a different delivery schedule.

Levine teaches different sets of parameters (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. dosage and frequency amount of a medication), each set of parameters defining a different delivery schedule (pg. 2, par. [0038], pg. 11, par.

[0147] and Fig. 23; i.e. each row represents individual medications, and dosages and frequency amounts of each individual medication).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include each row relating to a different set of operating parameters, each set of operating parameters defining a different operation for the device to provide enhanced control of the delivery of a medication over a period of time with precision and in a automated manner, without significant restriction on the user's mobility or lifestyle (Karmiy: pg. 1, par. [0007] and [0008]); and different sets of parameters, each set of parameters defining a different delivery schedule to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (Levine: pg. 1, par. [0009]).

14. As per claim 3, Estes teaches as set forth above the table comprising at least one cell within each row relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "at least one cell within each row relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name" as follows:

As per claim 3, Estes teaches a method substantially the same as claimed but does not expressly teach one cell within each row is relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row of as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Karmiy teaches one cell within each row relating to a unique identifying name (pg. 3, par. [0032] and Fig. 3, element 304g) wherein the unique identifying name identifies the parameters of the identifying name (pg. 3, par. [0034] and [0035] and Fig. 3, element 304h and 304i).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include one cell within each row relating to a unique identifying name wherein the unique identifying name identifies the parameters of the identifying name to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

15. As per claim 4, Estes teaches as set forth above downloading the operating parameters into memory (Fig. 2, element 106) on the pump (pgs. 3-4, par. [0035];

Art Unit: 2121

downloading the operating parameters from Fig. 2, element 132), the pump being programmed with a delivery schedule (pgs. 3-4, par. [0035]).

16. As per claim 5, Estes teaches as set forth above running the delivery program and, executing the operating parameters (pg. 8, par. [0073] and Fig. 6).

17. As per claim 6, Estes teaches as set forth above the method further comprising:
downloading all of the operating parameters to the infusion pump (pgs. 3-4, par. [0035] and Figs. 3A, element 300); and
storing the operating parameters in the memory (pgs. 3-4, par. [0035]).

18. As per claim 7, Estes teaches as set forth above selecting one unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program and executing at least some of the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "selecting one unique identifying and running the delivery program and executing at least some of the operating parameters identified by the selected unique identifying name" as follows:

As per claim 7, Estes teaches selecting one identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program and executing at least some of the operating parameters identified by the selected unique identifying name (pg. 6, par. [0057] and [0059]).

Estes does not expressly teach to a unique identifying name; and the operating parameters identified by the selected unique identifying name.

Karmiy teaches a unique identifying name (pg. 3, par. [0032] and Fig. 3, element 304g); and the operating parameters identified by the selected unique identifying name (pg. 3, par. [0034] and [0035] and Fig. 3, element 304h and 304i).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a unique identifying name; and the operating parameters identified by the selected unique identifying name to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

19. As per claim 10, Estes teaches the processor is further programmed to generate a plurality of rows in the table rows (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3).

Estes does not expressly teach each row relating to a different set of operating parameter, each set of operating parameters defining a different delivery schedule for the pump.

Karmiy teaches each row (pg. 2, par. [0029] and Fig. 3, element 302a-302g) relating to a different set of operating parameters (pg. 2, par. [0034] and [0035] and Fig. 3, element 304h and 304i), each set of operating parameters defining a different operation for the device (pg. 2, par. [0029]).

Karmiy does not expressly teach each set of parameters defining a different delivery schedule.

Levine teaches different sets of parameters (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. dosage and frequency amount of a medication), each set of parameters defining a different delivery schedule (pg. 2, par. [0038], pg. 11, par. [0147] and Fig. 23; i.e. each row represents individual medications, and dosages and frequency amounts of each individual medication).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include each row relating to a different set of operating parameters, each set of operating parameters defining a different operation for the device to provide enhanced control of the delivery of a medication over a period of time with precision and in a automated manner,

Art Unit: 2121

without significant restriction on the user's mobility or lifestyle (Karmiy: pg. 1, par. [0007] and [0008]); and different sets of parameters, each set of parameters defining a different delivery schedule to increase patient compliance, by replicating the experience of the patient visiting an actual clinic (Levine: pg. 1, par. [0009]).

20. As per claim 11, Estes teaches as set forth above each row in the table includes at least one cell relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

If, however the prior art is interpreted differently by a third party, the base reference and secondary reference teach "each row in the table includes at least one cell relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name" as follows:

As per claim 11, Estes teaches a method substantially the same as claimed but does not expressly teach each row in the table includes at least one cell relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Karmiy teaches each row in the table includes at least one cell relating to a unique identifying name (pg. 3, par. [0032] and Fig. 3, element 304g), wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name (pg. 3, par. [0034] and [0035] and Fig. 3, element 304h and 304i).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include each row in the table includes at least one cell relating to a unique identifying name, wherein the unique identifying name identifies the operating parameters in the same row as the unique identifying name to provide an improved and efficient techniques for generating instruction to control a device by providing users with the ability to directly edit cells of a table (pg. 1, par. [0004] and pg. 8, par. [0078] and [0079]).

21. Claims 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Estes in view of U.S. Patent No. 5,814,015 (hereinafter Gargano) in further view of U.S. Patent No. 5,719,761 (hereinafter Gatti).

22. As per claim 12, Estes teaches a method of operating an infusion pump (Fig. 1, element 100) for delivering a therapeutic agent into the body of a user (pg. 3, par. [0029]), the infusion pump being programmable (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132) and including memory (pgs. 3-4, par. [0035] and Fig. 1, element

106), the infusion pump being programmed to run a delivery program (pgs. 3-4, par. [0034] and [0035] and Fig. 2, element 132), the delivery program controlling the infusion pump to deliver the therapeutic agent according to a delivery schedule (pg. 3, par. [0032]-[0034], pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY), the method comprising:

storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

running the delivery program (pg. 8, par. [0073] and Fig. 6), the delivery program executing the set of operating parameters thereby controlling the infusion pump to deliver the therapeutic agent according to the delivery schedule defined by the set of operating parameters (pg. 6, par. [0057] and [0059]).

Estes teaches a method substantially the same as claimed but does not expressly teach selecting one user-defined identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected user-defined identifying name (pg. 6, par. [0057] and [0059]).

Gargano teaches a field for the selection of an identifying a name (col. 11, lines 40-47; i.e. the "drug name"); and running the delivery program wherein the delivery program executes the operating parameters identified by the selected identifying name (col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Gargano does not expressly teach to a user-defined identifying name.

Gatti teaches a user-defined identifying name for an infusion pump (col. 8, lines 30-39).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include a field for the selection of an identifying a name; and running the delivery program wherein the delivery program executes the operating parameters identified by the selected identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and a user-defined identifying name for an infusion pump to provide unique identifying name to a new configuration to avoid having mix of configurations with the same name (Gatti: col. 8, lines 40-44).

23. As per claim 13, Estes teaches as set forth above downloading the data set to the pump from a computer (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

Art Unit: 2121

24. As per claim 14, Estes teaches as set forth above the act of storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) further comprising storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

25. As per claim 15, Estes teaches as set forth above to generating a menu, the menu including at least one menu item corresponding to one of the user-defined identifying names; and the act of selecting the user-defined identifying name further comprising selecting the menu item (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

26. As per claim 16, Estes teaches as set forth above the act of storing a data set in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106) further comprising storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106)

Art Unit: 2121

includes storing a plurality of data sets in memory, each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

27. As per claim 17, Estes teaches as set forth above to generating a menu includes generating a menu having at least one menu item corresponding to a user-defined identifying name from one data set and at least one menu item corresponding to a user-defined identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

28. As per claim 18, Estes teaches as set forth above to the execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pg. 8, par. [0074]).

29. As per claim 19, Estes teaches an infusion pump (pgs. 2-3, par. [0027] and Fig. 1, element 100) comprising:

a pump mechanism (pg. 3, par. [0029]);

memory storing a data set (pgs. 3-4, par. [0035] and Fig. 1, element 106), the data set including a set of operating parameters defining a delivery schedule (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3), at least one of the operating parameters being a identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM); and

a processor (pg. 3, par. [0034]; e.g. PC, laptop) arranged to control the pump mechanism and in data communication with the memory (pgs. 3-4, par. [0034]), the processor being programmed to assign the set of operating parameters (pg. 6, par. [0054] and Fig. 3A; i.e. corresponding operating parameters and cells, e.g. Max Bolus: 5.7U, Time Display: 24 Hr., Beep Volume: 3) to the delivery program (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY) and to execute the set of operating parameters thereby controlling the pump mechanism to deliver the therapeutic agent according to the delivery schedule (pg. 8, par. [0073] and Fig. 6, BOLUS DELIVERY).

Estes teaches a method substantially the same as claimed but does not expressly teach the delivery program upon selection of the user-defined identifying name (pg. 7, par. [0063] and Fig. 5; i.e. Susp. On at 12:57 AM).

Gargano teaches the delivery program upon selection of the identifying name (col. 6, lines 19-30; i.e. selection the "drug name" initiates a delivery program).

Gargano does not expressly teach to a user-defined identifying name.

Gatti teaches a user-defined identifying name for an infusion pump (col. 8, lines 30-39).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of applicant's invention to modify the teaching of Estes to include the delivery program upon selection of the identifying name to provide a method of customization entry of drug information for a wide range of drug types and chemistries (Gargano: col. 1, lines 28-34); and a user-defined identifying name for an infusion pump to provide unique identifying name to a new configuration to avoid having mix of configurations with the same name (Gatti: col. 8, lines 40-44).

30. As per claim 20, Estes teaches set forth above a data port (pg. 3, par. [0034] and Fig. 2, e.g. PC, laptop), the processor being further arranged to control downloading of the data set and storage of the data set into the memory (pgs. 3-4, par. [0035], Fig. 1 and 2, elements 106 and 132 and Fig. 3A, element 300).

31. As per claim 21, Estes teaches as set forth above the memory further storing two or more data sets in the memory (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100,132; 0035, lines 1-7; Fig. 5, Alarm/Event Marker

Table; Page 6, [0060], lines 1-6, i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; Page 7, [0063], lines 1-13, i.e., "the time change is displayed in either 12 or 24 hr format depending on user's settings"; [0064], lines 13-15, i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

32. As per claim 22, Estes teaches as set forth above the processor being further programmed to:

generate a menu, the menu including at least one menu item corresponding to one of the unique identifying names, selecting the menu item being at least one step in beginning execution of the delivery program (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

33. As per claim 23, Estes teaches as set forth above the memory further storing two or more data sets (pgs. 3-4, par. [0035] and Fig. 1, element 106), each data set including a set of operating parameters defining a separate delivery schedule (Fig. 3A, element 300; Fig. 2, elements 100 and 132; pgs. 3-4, par. [0035]; Fig. 5, Alarm/Event Marker Table; pg. 6, par. [0060], i.e., "The graph is derived from carbohydrate consumption events from the event marker table that have been logged by the user"; pg. 7, [0063], i.e., "the time change is displayed in either 12 or 24 hr format depending

on user's settings"; pg. 7, par. [0064], i.e., "At least some of these events can be taken as inputs to the bolus estimator 128 in calculating an insulin dosage").

34. As per claim 24, Estes teaches as set forth above the processor being further programmed to generate a menu, the menu including at least one menu item corresponding to a user-defined identifying name from one data set and at least one user-defined identifying name from another data set (pg. 8, par. [0073] and Fig. 6, element "Main Menu").

35. As per claim 25, Estes teaches as set forth above the processor being further programmed to switch execution of the delivery program from the set of operating parameters in one data set to the set of operating parameters in another data set (pg. 8, par. [0074]).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER L. NORTON whose telephone number is (571)272-3694. The examiner can normally be reached on Monday-Friday between 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Albert DeCady can be reached on 571-272-3819. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/087,449
Art Unit: 2121

Page 30

/Albert DeCady/
Supervisory Patent Examiner
Art Unit 2121

/JLN/